K110736

510(k) Summary AUG 17 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Kira Gordon
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511 Benedict Ave,
Tarrytown, NY 10591

Date of Preparation: March 07, 2011

Name of Product: ADVIA® Chemistry Ferritin (FRT) Reagent
ADVIA® Chemistry Liquid Specific Protein Calibrator

FDA **Classification Name:** Ferritin immunological test system (Class II)
Calibrator (Class II)

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

New Product	Predicate Device	510(k) number	Device Class	Regulation	Product Code
ADVIA® Chemistry Ferritin (FRT) Reagent	N Latex Ferritin reagent	k993273	Class II	866.5340	DBF
ADVIA® Chemistry Liquid Specific Protein Calibrator	Randox Liquid Protein Calibrator	k061056	Class II	862.1150	JIX

Device Description:

The Ferritin reagents are ready-to-use liquid reagents. They are supplied in two different package sizes: 200 tests/wedge, 4 wedges/kit and 800 tests/wedge, 4 wedges/kit. In the ADVIA Chemistry Ferritin assay, sample is diluted and reacted with a buffer containing latex particles coated with antibody specific for ferritin. The formation of the antibody-antigen complex during the reaction results in an increase in turbidity, the extent of which is measured as the amount of light absorbed at 658 nm. By constructing a standard curve from the absorbance of standards, ferritin concentration of a sample can be determined.

ADVIA Chemistry Liquid Specific Protein Calibrator is a multi-analyte, liquid, buffer based product containing multiple analytes derived from human sources. The kit consists of 6 vials each of 6 calibrator levels which are ready for use (no preparation is required).

The constituent concentrations of these Calibrators are present at levels 2, 3, 4, 5 and 6. Level 1 is a zero level. The volume per vial is 1.0 mL.

Values for the new lots are assigned from a master lot that is referenced to the WHO 3rd International Standard IBSC 94/572

Intended Use:

The ADVIA Chemistry Ferritin reagent is for *in vitro* diagnostic use in the quantitative measurements of ferritin in human serum and plasma on the ADVIA Chemistry systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

The ADVIA Chemistry Liquid Protein Calibrator is for *in vitro* diagnostic use in the calibration of ADVIA® Chemistry system for the Alpha-Acid-Glycoprotein (AAG), Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Ferritin (FRT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), and Transferrin (TRF) methods

Comparison to Predicate Device:

Both the ADVIA Chemistry Ferritin reagent and the predicate N Latex Ferritin reagent employ prepackaged reagents for use on automated clinical chemistry test systems. A comparison of the important similarities and differences of these methods is provided in the following table:

Item	**New Device: ADVIA Chemistry Ferritin**	**Predicate Device: N Latex Ferritin**
Analyte	Ferritin	Ferritin
Intended Use	For in vitro diagnostic use in the quantitative measurement of ferritin	For in vitro diagnostic use in the quantitative determination of ferritin
Measurement	quantitative	quantitative
Sample type	Serum , Heparinized Plasma, EDTA plasma	Serum , Heparinized Plasma
Reference interval	Men: 20–250 ng/mL (20–250 µg/L) Women: 10–120 ng/mL (10–120 µg/L)	Men (n = 216): 20 - 290 µg/L Women, premenopausal (n = 193): 4.5 - 170 µg/L Women, postmenopausal (n = 47): 24 - 260 µg/L
Format	Liquid	Liquid
Use of Calibrators	Yes	Yes
Analytical measuring interval	6 – (450-500) ng/mL	Up to 640 ng/mL

Method Principle	turbidometric	nephelometry
Reagents	Two: R1 and R2	Three: Reagent, Supplementary A and Supplementary B
Instrument to be used	ADVIA 1650 Chemistry	BN System
Hook	Up to 40,000 ng/mL	Up to 10,000 ng/mL

Both the ADVIA Chemistry Liquid Specific Protein Calibrator and the predicate Randox Liquid Protein Calibrator are used in calibrations of ferritin on Chemistry systems. A comparison of the important similarities and differences is provided in the following table:

Item	**New Device: ADVIA Chemistry Liquid Specific Protein Calibrator**	**Predicate Device: Randox Liquid Protein Calibrator**
Intended Use	for *in vitro* diagnostic use in the calibration of ADVIA® Chemistry system for the Alpha-Acid-Glycoprotein (AAG), Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), **Ferritin (FRT)***, Haptoglobin (HAPT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), Transferrin (TRF) methods * - *subject of this submission*	Liquid Protein Calibrators are an in vitro diagnostic product used for the calibration of ASO, Complement C3, Complement C4, CRP, **Ferritin,** Haptoglobin, IgA, IgG, IgM, Prealbumin and Transferrin assays on Clinical Chemistry and Immunoassay systems
Instrument	ADVIA® Chemistry Systems	Abbott Spectrum, Abbott Aeroset, Abbott Architect *i*2000, Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron

		CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems.
Formulation / analytes present	Alpha-acid-glycoprotein Anti-streptolysin Alpha-1-Antitrypsin Ferritin Immunoglobulin A Immunoglobulin G Immunoglobulin M Immunoglobulin E Complement C3 Complement C4 Haptoglobin Microalbumin Myoglobin Prealbumin Rheumatoid Factor Transferrin CRP	Same
Measured Analytes (value assigned)	Alpha-acid-glycoprotein (AAG) Anti-streptolysin-O (ASO) Alpha-1-Antitrypsin (AAT) Ferritin (FRT) Immunoglobulin A_2 (IGA_2) Immunoglobulin G_2 (IGG_2) Immunoglobulin M_2 (IGM_2) Complement C3 (C3) Complement C4 (C4) Haptoglobin (HAPT) Prealbumin (PREALB) Rheumatoid Factor (RF) Transferrin (TRF)	ASO Complement C3 Complement C4 CRP Ferritin Haptoglobin IgA IgG IgM Prealbumin Transferrin
Form	Liquid	Same
Traceability for ferritin analyte	WHO 3rd International Standard IBSC 94/572	Same
Matrix	Buffered base	Same
Analyte source	Derived from human source	Same
Number of levels	Six (the lowest level is a zero-level)	Same
Fill Volume	1.0 mL each vial	Same

Stability	28 days open vial	30 days open vial

Comments on Substantial Equivalence:

Method Comparison between the ADVIA 1650 Chemistry Ferritin assay and N Latex Ferritin assay gave the following correlation statistics, when tested with patient samples:

Method Comparison Data
ADVIA 1650 Chemistry Ferritin vs. Predicate Method

New Device	Predicate Device	Slope	Intercept	n
ADVIA 1650 Chemistry Ferritin	N Latex Ferritin	1.00 (95% CI: 0.97 – 1.03)	0.00 (95% CI: -3.4 – 3.4)	47

Conclusion:

The ADVIA Chemistry Ferritin assay with the associated ADVIA Chemistry Liquid Specific Protein Calibrator is substantially equivalent in principle and performance to the N Latex Ferritin assay.

Kira Gordon
Regulatory Affairs & Compliance
June 24, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Siemens Healthcare Diagnostics, Inc.
c/o Dr. Kira Gordon
Senior Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

AUG 17 2011

Re: k110736

Trade/Device Name:	ADVIA ® Chemistry Ferritin Reagent ADVIA® Chemistry Liquid Specific Protein Calibrator
Regulation Number:	21 CFR §866.5340 21 CFR §862.1150
Regulation Name:	Ferritin immunological test system Calibrator
Regulatory Class:	Class II
Product Code:	DBF, JIX
Dated:	July 18, 2011
Received:	July 19, 2011

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110736

Device Name: ADVIA® Chemistry Ferritin Reagent
ADVIA® Chemistry Liquid Specific Protein Calibrator

Indications For Use:

The ADVIA® 1650 Chemistry Ferritin (FRT) Reagent:
For *in vitro* diagnostic use in the quantitative determination of ferritin in human serum and plasma on the ADVIA® 1650 Chemistry system. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

The ADVIA® Chemistry Liquid Specific Protein Calibrators: For *in vitro* diagnostic use in the calibration of ADVIA® Chemistry systems for the Alpha-Acid-Glycoprotein (AAG), Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), Ferritin (FRT), Haptoglobin (HAPT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), and Transferrin (TRF) methods.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K110736